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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,187	03/24/2004	Joseph S.M. Peiris	V9661.0078	4585

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EXAMINER	
MOSHER, MARY	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 04/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/808,187	PEIRIS ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 11-21, drawn to SARS diagnostic method, probes & primers used therein, classified in class 435, subclass 5. If this group is elected, election of species is further required, see below.

II. Claim 4, drawn to nucleic acid, classified in class 536, subclass 23.72. If this group is elected, election of species is further required, see below.

III. Claims 5-8, drawn to polypeptide, classified in class 530, subclass 350. If this group is elected, election of species is further required, see below.

IV. Claims 9-10, drawn to antibody, classified in class 530, subclass 387.9. If this group is elected, election of species is further required, see below.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP §806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute apparently distinct inventions for the following reasons:

For groups I and II, the probes and primers of group I have some structural relationship to the hybridizing nucleic acids of group II, in that they must share enough structure to hybridize under stringent conditions. However, the nucleic acids of group II can contain substantial amount of additional structure which cannot be predicted from the structure of the probes or primers. A reference teaching the probe would not

necessarily teach or suggest the characteristics of a larger nucleic acid which contains some complementary structure. Conversely, a reference teaching a large nucleic acid would not necessarily teach or suggest the useful characteristics of a specific oligonucleotide probe derived from the sequence. Furthermore, even though an oligonucleotide of group I may be a fragment of a group II nucleic acid, it is nonetheless a distinct chemical compound, just as benzene is distinct from naphthalene even though the structure of benzene is a fragment of the structure of naphthalene.

For groups I-IV, the polynucleotides of groups I-II, the polypeptides of group III, and the antibodies of group IV are chemically distinct products, separately classified having separate fields of search. The function and existence of either DNA or protein is not dependent on the existence of the other. The products of each group (I-II, III or IV) can be independently synthesized by chemical means. An antibody is encoded by an entirely different DNA than that of the protein which is bound by that antibody, and the primary sequence of the antibody bears no relationship to the sequence of the detected protein. The polynucleotides, polypeptides, and antibodies have separate, unrelated uses and are not disclosed as being capable of use together. Further, It would place undue burden on the examiner to examine several independent inventions in one application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their separate recognized divergent subject matter and the search for one group is not required for any other group, restriction for examination purposes as indicated is proper.

Election of Species

Group I contains claims directed to the following patentably distinct species of the claimed invention:

A. PCR assay using seqs 2471-73, claims 11, 14-16, 20, 1, 3 (in part)

B. PCR assay using seqs 2474-76, claims 12, 17-19, 21, 2, 3 (in part)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 13 is generic.

The species are patentably distinct because the probes and primers share no common structure, and detect different regions of the SARS genome.

Groups II-IV each are generic to a plurality of disclosed patentably distinct species comprising products hybridizing to, encoded by, or reacting with encoded products of the following species of nucleic acid:

A. SEQ 2471

B. SEQ 2472

C. SEQ 2473

D. SEQ 2474

E. SEQ 2475

F. SEQ 2476

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

The species are patentably distinct because each oligonucleotide hybridizes to a nucleic acid with a structure distinct from the others, encodes a polypeptide with a structure distinct from the others, and the polypeptide reacts with an antibody distinct from the others. A reference teaching one species of oligonucleotide, oligopeptide, or antibody would not permit one to predict the characteristics of any of the other species of oligonucleotides, oligopeptides, or antibodies, rendering each of them patentably distinct.

Should applicant traverse with any of the above species election requirements on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3/30/05

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER